

U.S.S.N.: 09/083,307  
Filed: May 22, 1998  
AMENDMENT

Sub C1  
B2  
Cancel

(b) an agent selected from the group consisting of anti-angiogenic compounds, procoagulant compounds, cytokines, chemotherapeutic agents, and radiation, in a dosage formulation for treatment of the patient in combination with treatment of the patient with the device to remove blood components having a molecular weight of 120,000 daltons or less.

### Remarks

#### **Objections to the Specification and Rejections under 35 U.S.C. §112**

The typographical errors in the specification have been corrected. The Examiner's careful review is appreciated.

The specification has been rejected as non-enabling. This rejection is respectfully traversed.

• There is no legal requirement to provide the mechanism by which a claimed method works. The applicant has provide multiple actual working examples demonstrating actual reduction to practice. The applicant has provided details as to how to practice the claimed method, suppliers for the various devices and reagents, and advised how to put these components together in order to treat patients.

With regard to the comments regarding the "presumed mechanism", the examiner is in error. Page 11, lines 20-23, notes that the filtration process removes the majority of the soluble receptor molecules that inhibit the patient's ability to fight the cancer. Removal of the inhibitors allows the patient to kill off the tumor. The adjuvant therapy unexpectedly enhances and maintains the process, allowing in some cases for complete remission. See also, page 9, lines 10-14.

Claim 8 has been amended to make it clearer that the vaccine is made by immunization against the epitopes unique to the diseased, infected or transformed tissue. These vaccines are